

HF1-35 (purged)

9/2/97
EF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration 516

Refer to: CFN 1125051

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

August 7, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Trower, President
Water and Health of Chesapeake, Inc.
d/b/a 1st Choice Water Company
3133 Western Branch Boulevard
Chesapeake, Virginia 23321

Dear Mr. Trower:

An inspection of your bottled water facility conducted by the Food and Drug Administration on July 11 through 17, 1997, documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Part 110) and the Processing and Bottling of Bottled Drinking Water Regulations, Part 129. By virtue of these deviations, the product processed at your facility is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, as follows:

1. Failure to adequately clean and sanitize each multi-service water container prior to being filled, capped, and sealed.
2. Failure to have an adequate sanitizing operation designed to sanitize the intended water product contact surfaces and any other critical area of the water containers.
 - a. No records are available to demonstrate that your procedure to sanitize the water containers with a [REDACTED] solution is equivalent in bactericidal action to a 2-minute exposure of 50 parts per million (ppm) of available chlorine at 57°F.

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- b. No records are available to document that [REDACTED] used to sanitize water containers is, at a minimum, a 0.1 ppm ozone water solution in an enclosed system for at least 5 minutes.
3. Failure to document maintenance of the [REDACTED] generators used to sanitize product water-contact surfaces. For example, no records are available for the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment.
4. Failure to assure that each person engaged in the bottling of drinking water has adequate training to perform their assigned function. For example, your training failed to include container washing and the maintenance of [REDACTED] generators.
5. Failure to test the source water at a minimum frequency of once per year for chemical contaminants, in that no certificate showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants exists for the source water from a public water system.
6. Failure to identify each unit package from a batch or segment of a continuous production run of bottled drinking water with a production code.
7. Failure to adequately test, at least once a week for bacteriological purposes, a representative sample from a batch or segment of a continuous production run, for each type of bottled drinking water produced during a day's production.
8. Failure to test, at least annually for chemical, physical, and radiological purposes, a representative sample from a batch or segment of a continuous production run, for each type of bottled drinking water produced during a day's production.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations.

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Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at 804-379-1627, ext. 14.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

cc: Virginia Department of Agriculture and Consumer Services
1100 Bank Street
P.O. Box 1163
Richmond, Virginia 23209